

Do the formulants used in Btk products pose health risks?

In addition to the active ingredient Btk, other ingredients (formulants) are used to create the final product. These normally include water and ingredients to make the product stick to leaves and needles of trees. Studies carried out in many different countries have indicated that there are no significant health risks from any of the ingredients in Btk products.

What is the effect of Btk on the environment?

Btk only becomes toxic in the alkaline gut of specific lepidopteran insects in the larval (caterpillar) stage of their life cycles. Because of this, it does not affect adult moths and butterflies, other insects, honeybees, fish, birds or mammals. The United States Environmental Protection Agency categorizes the risks posed by Bt strains to non-target organisms as *minimal to non-existent*. The insecticidal toxin biodegrades quickly in the environment through exposure to sunlight and microorganisms. This takes between 1 and 4 days on foliage. There are no groundwater contamination concerns, as Btk does not percolate through the soil beyond 25cm.

How can you be sure that Btk is not affecting health or the environment?

Environmental and health monitoring is carried out by federal and provincial scientists after spraying programs to evaluate any possible effects on humans or the environment. Even with the many years of widespread use of Btk in forestry, agriculture and urban settings, no public health problems have been identified, nor have any significant environmental concerns been raised.

Bt strains have been used by both organic and non-organic farmers throughout the world for many years. Bt is one of the few pesticides acceptable to organic growers, as it is a naturally occurring biological organism, rather than a synthetic chemical. As Bt does not survive in warm-blooded organisms, any Bt residues on food pass through the digestive system without producing any toxic effect. Bt strains are exempt from residue tolerances in the United States and exempt from maximum residue limit requirements in Canada because of the minimal risk.

Contact provincial forestry or natural resources officials regarding any concerns you may have about spray programs in your area.

For more information about pest control products, contact the PMRA at 1-800-267-6315 or at (613) 736-3799 (outside of Canada). You can also visit our web site at <http://www.hc-sc.gc.ca/pmra-arla>.

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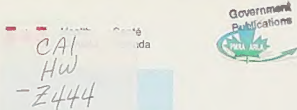
Fact Sheet on the *Bacillus thuringiensis* subspecies *kurstaki*

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B*acillus thuringiensis* subspecies *kurstaki*, commonly referred to as Btk, is a bacterium found naturally in soils. For some 30 years, it has been used successfully worldwide as a biological pest control agent to combat a variety of forestry and agricultural insect pests.

How does Btk work?

The Btk bacterium produces a protein crystal during the spore-forming stage of its life cycle, which is toxic only to the larvae (caterpillars) of specific insect species. These microscopic crystals are ingested by insects when they are feeding on foliage treated with Btk. In the alkaline environment of the susceptible insect's digestive system, the crystals are converted into toxic protein molecules that destroy the walls of the insect's stomach. The insect usually stops feeding within hours and dies within 2–5 days.

Btk works only against a group of insects called lepidopterans, which includes destructive tree pests such as gypsy moths, spruce budworms and forest tent caterpillars. These pests are responsible for defoliating many trees in both urban areas and in forests. Other subspecies of Bt are registered for commercial use in Canada and these too work only on specific species of insects. For example, Bt subspecies *israelensis* (Bti) is active solely on mosquito and blackfly larvae; Bt subspecies *tenebrionis* (Btt) on Colorado potato beetles.

How is Btk used?

Btk in its various formulations can be applied using both ground and aerial spray methods. Aerial spraying may be used in forestry and urban areas to ensure adequate coverage and effectiveness. Btk has been used on millions of acres of wooded areas and agricultural crops in many countries worldwide. Btk products are used in Canada to control gypsy moth, spruce budworm and other specific pests in forestry and urban settings, as well as certain insects that feed on vegetable and fruit crops.

What is the role of the Pest Management Regulatory Agency in regulating Btk?

Health Canada's Pest Management Regulatory Agency (PMRA) is responsible for ensuring the human health and environmental safety of all pest control products prior to their approval for use in Canada. Manufacturers must provide the Agency with a full analysis of the product formulation, as well as extensive health and environmental data, so that a risk assessment can be carried out by PMRA scientists. Only products that are scientifically reviewed and found to be effective and safe for use with minimal risk to human health and the environment are registered by the PMRA.

In Canada, the PMRA has classified all Btk products registered for use in forests, woodlands and residential areas as "restricted." Restricted class products require special permits or licensing from the regulatory authority in the province or territory for purchase. In the case of Btk, provincial or territorial regulatory authorities are consulted before any application takes place, and they must issue permits for the product's use. In addition, only applicators who have passed a provincial certification exam may use Btk products.

Are there health concerns related to the spraying of Btk?

Btk poses little threat to human health through either handling products directly or being exposed to them indirectly such as during a spray program. For Bt toxins to be activated, alkaline conditions that exist only in certain insects' digestive systems must be present. The acidic stomachs of humans and animals do not activate Bt toxins. There have been no documented cases involving toxicity or endocrine disruption potential to humans or other mammals over the many years of use in Canada and around the world. Studies have shown that even if Btk spores are ingested or inhaled, they are eliminated without any adverse health effects.

Prior to being permitted for sale or use in or import into Canada, all formulations are evaluated according to internationally accepted scientific protocols for their potential to cause

skin or eye irritation or sensitization and acute toxic effects. These tests are designed to show if the product has the ability to produce health effects or trigger allergic-type reactions.

The fact that Btk is a naturally occurring, widely distributed organism in the environment means that the average person would have multiple exposures to this biological agent throughout their lifetime, even if they never came in contact with a formulated product. Some unprotected spray workers, who were exposed to up to 500 times more Btk than the average person would be during a spray program, experienced only minor skin, eye or respiratory irritation. Members of the public are unlikely to experience *any* symptoms if inadvertently exposed to Btk spray, and no special precautions are necessary or required. Individuals who have concerns, however, should take reasonable precautions to avoid exposure during a spray program in the same way they would avoid pollen or other airborne materials during days when air quality advisories are issued. They can also reduce exposure by staying indoors with windows and doors shut during the spray period if spraying is taking place in their area, although this is not required by health officials.